

## **H.12 CONTRACT VIOLATIONS OR INTEGRITY ISSUES**

The QIO shall disclose to CMS whenever a known, probable or suspected violation of law or rule, or violation of a contract term or provision, is discovered. Disclosures to CMS must be in accordance with the procedures set forth below.

Incidents requiring disclosure to CMS under this provision means a situation, act, or failure to act involving the following:

- (1) a matter that a reasonable person would consider a violation of criminal, civil or administrative laws applicable to any Medicare contract or Federal health care program; or
- (2) integrity violations, including any known, probable or suspected violation of any Medicare contract term or provision. An incident requiring disclosure to CMS may be the result of an isolated event or a series of occurrences. Incidents that are subject to disclosure to CMS under these procedures include any situation, act or failure to act that occurs at the QIO or any of its subcontractors, consultants, vendors or agents.

If a QIO discovers, through any means, a known, probable or suspected incident requiring disclosure to CMS, the QIO must provide to CMS a written disclosure within 30 days of discovering the incident. Within 45 days of the date of the initial disclosure, the QIO must provide to CMS a written final investigative disclosure on the incident. If a QIO is unable to complete its investigation within this 45-day period, the QIO must provide to CMS a written request for an extension of time to complete its investigation and submit its final disclosure. The request for an extension of time must specify the reasons for the request.

The written disclosure must include the following information:

- (1) If the incident is the result of a probable or possible violation of criminal, civil or administrative law or a violation of a contract term or provision, the disclosure must describe the incident with as much specificity as possible, including the following:
  - (i) The law, regulation or contract term implicated.
  - (ii) The persons involved and the department(s) within the QIO operation that is (are) affected.
  - (iii) The time period of the incident.
  - (iv) A determination as to whether the incident has affected, or is affecting performance under the contract.
  - (v) Any corrective action taken, or intended to be taken, by the QIO.
- (2) If the incident results in an overpayment, relating to either Trust Fund payments or administrative costs, the disclosure must describe the overpayment with as much specificity as possible as of the time of the due date for the submission of the disclosure, including the following:

- (i) The amount of the overpayment. If the overpayment has not yet been quantified, the QIO must provide its best estimate of the amount of the overpayment.
- (ii) The nature of the overpayment and the reason for the overpayment.
- (iii) The time period of the overpayment.
- (iv) Any corrective action taken, or intended to be taken, by the QIO.
- (v) Repayment of the overpayment, which must be done in accordance with CMS policies and procedures.

The final written disclosure must include the following information:

- (1) The disclosure must address all the required information for the initial written disclosure, as described above.
- (2) A statement as to whether the QIO considered changing any policies and procedures or retraining of employees to prevent the recurrence of this or other similar incidents. If policies and procedures were changed, or retraining occurred, or will occur, the QIO must describe the changes and/or the training that has been done or will be done in the future.
- (3) A corrective action plan prepared in accordance with CMS policies and procedures.
- (4) A statement that the QIO's internal investigative file on the incident is available to CMS for audit, inspection or reproduction.
- (5) The name(s) of the person(s) who conducted the investigation.

Both the initial and final disclosures shall be submitted to the CMS Contracting Officer and the CMS Compliance Office of the Office of Acquisition and Grants Management.